

B4
cont
Sub
C1
and wherein, if said dosage form is a capsule, said buffer is implemented to contain 0.1 mg/mL of trypsin.

B2
cont
Sub
C1
96. A delayed release dosage form comprising azithromycin which meets the following in vitro criteria:

in a first dissolution stage, $Q_{0.25} < 10\%$ when said dosage form is inserted in a USP rotating paddle apparatus, said apparatus being described in USP XXIII dissolution test chapter 711, and wherein said apparatus has paddles rotating at 50 rpm and contains 750 mL of 0.1 N HCl at 37°C;

in a second dissolution stage, $Q_{0.5} < Q_{0.25} + 10\%$ when 250 mL of 0.2 M tribasic sodium phosphate buffer is added to said acid immediately following said first stage to implement a buffer having a pH of about 6.8.

B3
125. A sustained release dosage form comprising azithromycin for ingestion by a mammal which meets, based on the weight of said mammal, the following in vitro criteria:

- (1) $Q_{0.25} \leq 4$ mg/Kg of mammal weight,
- (2) $Q_1 \leq 10$ mg/Kg of mammal weight,
- (3) $Q_2 \leq 20$ mg/Kg of mammal weight,
- (4) $Q_4 \leq 30$ mg/Kg of mammal weight, and
- (5) $Q_6 \leq 40$ mg/Kg of mammal weight,

when said dosage form is tested in a USP rotating paddle apparatus, said apparatus being described in USP XXIII dissolution test chapter 711, and wherein the apparatus has paddles rotating at 50 rpm and contains 900 mL of pH 6.0 sodium dihydrogen phosphate buffer at 37°C;

and wherein, if said dosage form is a capsule, said buffer is implemented to contain 0.1 mg/mL of trypsin.

REMARKS

The amendments have been made to improve form, as further discussed below. Claims 72, 96, and 125 have been amended to make it clear that Applicants' claimed dosage forms contain azithromycin. Sheets entitled "VERSION MARKED UP TO SHOW CHANGES MADE" are appended hereto to show the exact nature of the amendments.